

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

BRECKENRIDGE PHARMACEUTICAL, INC.,

Plaintiff,

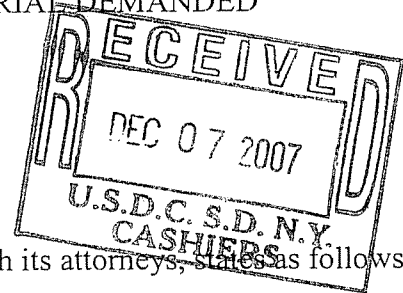
v.

MIDLAND HEALTHCARE, LLC,

Defendant.

) JUDGE SWEET
)
)
)
) 07 CV 11114
) Civil Action No. 11114

) JURY TRIAL DEMANDED
)
)
)



COMPLAINT

Plaintiff Breckenridge Pharmaceutical, Inc., by and through its attorneys, states as follows
for its Complaint against Defendant Midland Healthcare, LLC:

The Parties

1. Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a corporation existing under the laws of the State of Florida, with its principal place of business at 1141 South Rogers Circle, Suite 3, Boca Raton, Florida.
2. Breckenridge is a developer, marketer and distributor of pharmaceutical products sold under its own Breckenridge label.
3. Defendant Midland Healthcare, LLC ("Midland") is a limited liability company existing under the laws of the State of Kansas, with its principal place of business at 1201 Douglas Avenue, Kansas City, Kansas 66103. Upon information and belief, none of the members of Midland are citizens of the State of Florida.
4. Midland is in the business of developing, manufacturing, and selling pharmaceutical products.

Jurisdiction and Venue

5. This is a claim for breach of contract under New York law. Jurisdiction is based on 28 U.S.C. § 1332, as the parties are of diverse citizenship and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because, upon information and belief, Midland has significant commercial contacts with this judicial district, and also because Midland agreed in the contract at issue that venue shall lie in the State of New York.

Statement Of Facts

7. In or about late 2006, Breckenridge began negotiations with Midland with the purpose of retaining Midland to develop an Abbreviated New Drug Application (“ANDA”) for a particular prescription drug (the “Product”) to be filed with the United States Food and Drug Administration (“FDA”) on behalf of Breckenridge, and also to serve as the exclusive manufacturer of the Product for Breckenridge upon FDA approval.

8. Accordingly, on January 26, 2007, Breckenridge and Midland entered into an ANDA Development, Manufacture, and Supply Agreement (the “Agreement”). A copy of the first page and signature page of Agreement are attached as Exhibit A, with confidential and trade secret information redacted.¹

9. In the Agreement, Midland undertook to “be wholly responsible for the development of the Product.” Agreement, § 2.1(a).

10. In the competitive marketplace of generic drug products, time is of the essence in the development of ANDAs and their submission to the FDA for approval. Thus, as a key part of the Agreement, Midland agreed to meet certain “milestones” on the timetable included in Exhibit

¹ Because of the confidential nature of the Agreement, a full copy will be filed under seal at an appropriate time, upon approval of the requisite motion.

B to the Agreement.

11. Midland also agreed to provide Breckenridge with monthly status reports.

Agreement, § 2.3.

12. Midland has failed to meet the agreed milestones, has failed to submit at least two monthly status reports, and has moreover misrepresented its progress on the milestones.

13. Breckenridge has thus far paid \$200,000 to Midland, in return for which it has not received the ANDA or the development of the Product for which it contracted.

14. In addition, the time at which Breckenridge can bring the Product to market has been unreasonably delayed by Midland's actions.

15. Furthermore, Breckenridge has now been informed that Midland intends to sell, or otherwise consummate a transfer of, its assets by January 20, 2008.

COUNT I

16. Breckenridge incorporates the allegations of the preceding paragraphs as though fully set forth herein.

17. By reason of the foregoing, Midland has breached the Agreement, and Breckenridge has been injured thereby, in an amount to be proved at trial.

PRAYER FOR RELIEF

WHEREFORE, Breckenridge requests that the Court:

(a) Preliminarily and permanently enjoin Midland, along with its members, managers, officers, employees, and agents, from selling, or otherwise transferring or disposing of, the assets of Midland prior to the resolution of this dispute;

(b) Enter judgment for Breckenridge against Midland for such compensatory damages as Breckenridge shall prove at trial, adequate to compensate Breckenridge for Midland's breaches of the Agreement; and

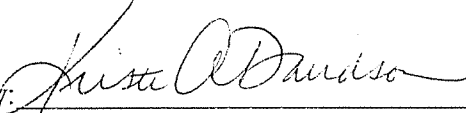
(c) Enter an Order granting Breckenridge such other and further relief as the Court deems proper and just.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Breckenridge demands a trial by jury of all issues properly triable to a jury in this case.

Dated: December 7, 2007
New York, New York

BUCHANAN INGERSOLL & ROONEY PC

By: 

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ANDA DEVELOPMENT, MANUFACTURE, AND SUPPLY AGREEMENT

ANDA for [REDACTED] (generic of [REDACTED])

THIS AGREEMENT entered into as of this 26th day of January, 2007 by and between BRECKENRIDGE PHARMACEUTICAL, INC., a Florida corporation with a principal place of business at 1141 S. Rogers Circle, Suite 3, Boca Raton, FL 33487 ("Breckenridge") and MIDLAND HEALTHCARE LLC, 1201 Douglas Avenue, Kansas City, KS 66103 (hereinafter referred to as "Midland") (hereinafter collectively the "Parties")

WHEREAS, Breckenridge is engaged in the business of developing, marketing and selling pharmaceutical drug Product;

WHEREAS, Midland is engaged in the business of developing, manufacturing, and supplying pharmaceutical drug Product;

WHEREAS, Midland desires to provide to Breckenridge and Breckenridge wishes to obtain certain product development services in connection with the submission and sponsorship of an ANDA for [REDACTED] and, upon FDA approval, which will be contract manufactured exclusively by Midland for and sold exclusively by Breckenridge;

NOW, THEREFORE, for the consideration and covenants set forth herein, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

SECTION I - DEFINITIONS

1.1 ANDA. The acronym, Abbreviated New Drug Application, as defined in section 505(j) of the Federal Food Drug & Cosmetic Act, as amended.

1.2 ANDA Approval. The date on which Breckenridge receives either the approval letter, or tentative approval letter, from the FDA that the Product submitted meets applicable standards required for ANDA's.

1.3 ANDA Filing. The date on which Breckenridge receives the letter from the FDA confirming acceptance of the ANDA submission.

1.4 Affiliate. Any corporation or other legal entity whereby fifty percent (50%) or more of its voting capital shares or similar voting securities is owned by one of the Parties.

1.5 API. The acronym, active pharmaceutical ingredient.

1.6 Completion of Biostudies. If required as part of the ANDA submission, the date of receipt of a final report relating to an FDA-compliant clinical bioequivalence study (with protocol approved by the Office of Generic Drugs, if applicable) utilizing a completed Exhibit Batch and predetermined acceptance criteria.

1.7 Completion of Formulation Development. The successful manufacture of a pilot-scale batch, receipt by Breckenridge of acceptable comparative assay results for the pilot-scale batch, and successful completion of analytical method validation, including impurities.

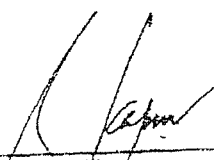
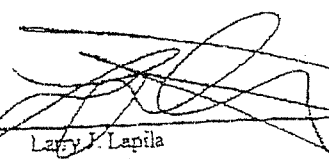
1.8 Completion of Scale-Up. The successful manufacture of the ANDA Exhibit Batch and receipt by Breckenridge of acceptable comparative assay results.

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IN WITNESS WHEREOF, each of Breckenridge and Midland have executed this Agreement by their duly authorized officers as of the date first set forth above.

MIDLAND HEALTHCARE LLC	BRECKENRIDGE PHARMACEUTICAL INC.
By: 	By: 
Name: Ramon Kapur	Name: Larry J. Lapila
Position: Chairman	Position: Vice President Business Development
Dated: January 26, 2007	Dated: January 26, 2007

Civil Action No.

BRECKENRIDGE PHARMACEUTICAL, INC.,

Plaintiff,

-against-

MIDLAND HEALTHCARE, LLC,

Defendant

COMPLAINT

BUCHANAN INGERSOLL & ROONEY PC
ONE CHASE MANHATTAN PLAZA, 35TH FL
NEW YORK, NEW YORK 10005
(212) 440-4400

Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information and belief and reasonable inquiry, the contentions contained in the annexed document are not frivolous.

Dated:..... Signature.....

Print Signer's Name.....

Service of a copy of the within is hereby admitted.

Dated:.....
.....
Attorney(s) for

PLEASE TAKE NOTICE

☐ that the within is a (certified) true copy of a
Notice of Entry entered in the office of the clerk of the within named Court on

☐ that an Order of which the within is a true copy will be presented for settlement to
Notice of Settlement the Hon. one of the judges of the within named Court,
at
on , at M.

Dated:

BUCHANAN INGERSOLL & ROONEY PC
ONE CHASE MANHATTAN PLAZA, 35TH FL
NEW YORK, NEW YORK 10005
(212) 440-4400